It is known that psoriasis patients skin cannot perform one basic function i.e. prevention of water and heat loss from the skin. Total water loss (TWL) of psoriatic skin is about 6-8 times higher than normal healthy skin. The only way to protect the water and heat loss is by causing vasoconstriction to the skin or giving a protective layer. This layer would control water and heat loss and help in self-repair process of the skin.

Dermist Shampoo is a special formulation directed toward removal of scales on the scalp and body while having shower with lukewarm water with minimum effort.

Dermist Cream is formulated to give a protective layer to the psoriasis affected and exposed skin by removing scales. By applying Dermist cream immediately after the shower a protective layer with form on the skin, which will protect the skin from water and heat loss and pathogens from entering into exposed skin.

2B. Study Procedures

Study Duration:

- The total duration of the study for each individual patient was 12 weeks.
- Screening was completed in one week then a wash out period was given to each patient, where they were not allowed to apply any topical sterolds. All the selected patients had to visit the test site on screening (1st week) then again for a check up on the 2nd, 4th, 6th, 8th, 10th, and 12th week, for a total of 8 visits.
- During these 8 visits patients were provided with the study agent and were given instructions on the desired method of application. Subject compliance with protocol was asserted by collecting the empty tubes and containers. Subjects were also provided with sheets to document their usages daily. (The study procedures and study agent usage by subjects are enclosed in annex.)

Number of Subjects Studied:

- Based on the inclusion and exclusion criteria, the total number of subjects enrolled in the study was 42.
- Of these 42 subjects, two subjects dropped out in the second visit due to lack of study compliance.

Method of Application:

- Dermist Shampoo: Wash the Psoriasis affected area of skin/scalp once a day while having shower; preferably in the morning.
- Dermist Cream: Apply 2-3 times a day on Psoriasis affected area of the skin/scalp. This should be done after washing with Dermist Shampoo (once a day and then with normal water in other times) and then after the skin/scalp has been patted dry with a cotton towel.

2C. Dermatology Quality of Life Index

The subject was evaluated on the scale of personal satisfaction (as excellent, good, or bad) after using the medication.

The health related quality of life was assessed using "Dermatology Quality of Life". The DOQL has been used in a number of studies of dermatological diseases including eczema, chronic idiopathic urticaria and psoriasis to evaluate the impact of treatment in these patients. It has been developed as a brief questionnaire for routine clinical use to assess the limitations related to the impact of skin disease and has been shown to be responsive to clinical changes in a study of dermatology

2D. Side Effects

Recoding of side effects began on 3rd visit. The characters of side effects noted and the summary evaluation of those side effects was done at the completion of the study. Both cutaneous and ophthalmologic side effects were particularly noted.

2E. Study Results

Study Start date: 26.03.08
Study end date: 2.11.08
Total number of patients included in the study: 42
Patients dropped: 2
Total number of patients completed the study: 40

Demographics of the subjects:

Age of subject

- Range: the youngest patient was 21 years and the oldest patient was 63 years
- Mean age: 42 years

Gender Distribution

- Total number of males was 30 therefore 71.4%
- Total number of females was 12 therefore 28.6%

Characteristics of the psoriasis in the subjects selected:

- The mean disease duration of psoriasis was 10.5 years.

At each visits the PASI scores were calculated. And the evaluation of the improvement and hence the efficacy were evaluated at the end of the study. The mean PASI scores after each visit were as follows. (Table 1).

No. of visit	% decrease in PASI	Mean % cured	PASI score
Screening	100%	0%	9.3
Visit 1	100%	0%	9.3
Visit 2	81.5%	19%	7.5
Visit 3	68.1%	31.6%	6.3
Visit 4	53.2%	46.8%	4.9
Visit 5	41.3	58.7%	3.8
Visit 6	35.8	64.2%	3.3
Visit 7	29.3	70.7%	2.7

Table 1. Mean PASI Score

2F. Evaluation of Results

Efficacy was mentioned by two end points.

The PASI scores evaluation of improvements:

- Worsened
- Not improved
- Moderate improvement
- Good improvement
- Outstanding improvement

Dermatological quality of life index evaluation of improvements:

- Very much
- A lot
- A little
- Not at all

The PASI scores:

Worsened	PASI score higher than baseline
Not improved	PASI decrease 0-25%
Moderate improvement	PASI decrease 26-50%
Good improvement	PASI decrease 51-75%
Outstanding improvement	PASI decrease 76-100%

Changes noted in the subjects as per PASI scores:

Worsened ---------- 0
Not improved---------- 1 (2.5%)
Moderate improved ---------- 5 (12.5%)
Good improvement ---------- 7 (17.5%)
Out standing improvement---------- 27 (67.5%)

Subjective evaluation by the subjects in efficacy:

Very much ---------- 6
A lot ---------- 21
A little ---------- 12
Not at all ---------- 1

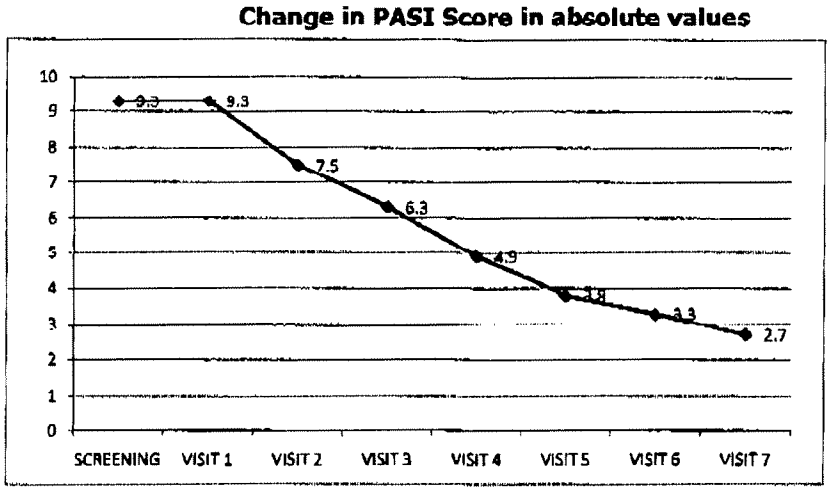


Figure 1.

2G. Discussion and Conclusion

Discussion:

- The study was completed on 40 of the 42 subjects that originally started. The 2 subjects dropped out due to lack of compliance. The study was performed on patients who fulfilled the inclusion and exclusion criteria. Care was only taken on stable patients. Patients with extreme, unstable or erythrodermic psoriasis were not considered.
- The minimum PASI score was equal to or greater than two, in at least one region at the time of screening. Psoriasis was confirmed using histopathological examination of the skin. Biopsy specimens were required after taking an informed consent form. In other subjects the diagnosis was made on clinical grounds. The mean duration of psoriasis was 10.2 years. Response was graded at each visit using PASI score and the patient self assessment.
- Side effects were specifically asked and noted by the physician. In this study no side effects or adverse events were noted during the entire course of the study.
- Improvement was noted on basis of PASI scores at each visit. A 19% improvement in mean PASI score was noted at the 2nd visit, 31.6% at the 3rd visit, 46.8% at the 4th visit, 58.7% at the 5th visit, 64.2% at the 6th visit,and 70.7% at the 7th visit. The overall mean at the end of the study (the mean PASI score) was in the range of good improvement.
- Based on PASI scores, only one patient did not significantly improve, although they were symptomatically better at the end of the study. Patient had few lichenfied plaques; this being the reason for the insignificant improvement for some patients.
- Five patients (12.5%) had moderate improvement, one patient (17.5%) had good improvement and 27 patients (67.5%) had outstanding improvement. In the entire study, nine patients had more than 90% improvement. Three patients with low PASI scores in range of 2-5 had localized plaque psoriasis at screening had and had 100% response at completion of trial.
- Subject improvement was marked as very much in six patients, and a lot of improvement in 21 patients. This implies that these patients improvement correlated with moderate to good seen by the evaluation for PASI scores. Twelve patients had little improvement and as previously mentioned one patient had not improved at all.

Conclusion:

- The product was concluded as having a significant clinical improvement for monotheraphy in patients with psoriasis. There were no side effects noted during the entire study. Hence it is concluded as a safe and effective method of treating psoriasis. Though the author feels that being not a controlled study this study has its own limitations and should be followed up by more controlled studies to further understanding.

3rd Group 16 patients

7 treated in association with Exilite 308 nm
11 treated with Psoria only, twice a day

First monitoring 35 days of treatment

75% Positive positives Association
60% Psoria only

Second monitoring 70 days of treatment

85% Positive positives Association
75% Positive Psoria only

I pazienti sottoposti allo studio presentano le seguenti caratteristiche:

- psoriasi a placche moderata e/o grave
- età compresa tra 30 e 65 anni
- trattamento concomitante con farmaci biologici (Humira o Enbrel)
- presenza di lesioni su sedi simmetriche

N° paziente	Sesso	Età	Sede	Giorni di applicazione	Risultato
1	M	55	Emitorace sx	30	+++
2	M	54	Mano dx	30	++
3	F	40	Dorso inf.	30	+
4	M	51	Gomito dx	30	+
5	M	45	Gomito sx	30	+
6	F	48	Fianco sx	30	+++
7	M	60	Emitorace sx	30	+++
8	M	32	Ginocchio dx	30	+
9	F	53	Gomito sx	30	0
10	M	46	Dorso inf.	30	+
11	F	31	Gomito sx	30	0
12	M	55	Gomito dx	30	+
13	F	63	Ginocchio sx	30	0
14	M	46	Mano dx	30	++
15	F	39	Mano sx	30	++
16	F	30	Fianco sx	30	+++
17	F	56	Ginocchio sx	30	0
18	M	58	Gomito dx	30	+
19	F	65	Gomito sx	30	0
20	M	64	Gomito dx	30	0
21	F	59	Fianco dx	30	+
22	M	57	Emitorace sx	30	+++
23	F	46	Fianco dx	30	+++
24	M	31	Mano dx	30	0
25	M	35	Mano sx	30	++
26	F	35	Fianco sx	30	+
27	F	64	Fianco dx	30	++
28	M	58	Gomito dx	30	+
29	F	52	Ginocchio sx	30	+
30	M	58	Mano dx	30	++
31	F	56	Fianco sx	30	+++
32	M	46	Gomito dx	30	0
33	M	44	Mano sx		-
34	F	45	Gomito sx		-
35	M	41	Emitorace dx		-
36	M	58	Mano dx		-
37	F	56	Fianco sx		-
38	M	46	Gomito dx		-
39	M	44	Mano sx		-
40	F	45	Gomito sx		-

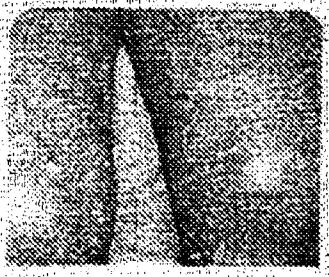
LEGENDA:
0 nessun miglioramento/peggioramento
+ lieve miglioramento
++ moderato miglioramento
+++ ottimo miglioramento
- mancato ritorno al controllo clinico

I dati fanno riferimento all'applicazione della crema su lesioni di un emilato dx e/o sn con confronto, dopo 30 giorni, dell'emilato controlaterale non trattato.

PSORIASIS Study #1

Enrolled 46 Patients: 36 males, 10 females
Age between 23 and 62 years old.
10-week treatment

Erythrodermic psoriasis



Psoriasis vulgaris

1st Group	12 patients	*Erythrodermic psoriasis*	9 males/3 females
2nd Group	16 patients	*Psoriasis vulgaris*	12 males/4 females
3rd Group	18 patients	*Relapsed Psoriasis*	15 males/3 females

Divided in 3 groups

21 patients treated in association with Excilite 308 nm 92.8% positive
25 patients treated with Psoria only, twice a day 78% positive

28 of these patients have exposed themselves to sunlight during the Summer treatment for about 2 weeks.

Excilite
http://www.cosmetology.medeks.az/equipment_en.inc.php?menu&page=24

1st Group 12 patients
7 treated in association with Exilite 308 nm
5 treated with Psoria only, twice a day

First monitoring 35 days of treatment
80% Positive positives Association
65% Psoria only

Second monitoring 70 days of treatment
95% Positive positives Association
80% Positive Psoria only

2nd Group 16 patients
7 treated in association with Exilite 308 nm
9 treated with Psoria only, twice a day

First monitoring 35 days of treatment
85% Positive positives Association
65% Psoria only

Second monitoring 70 days of treatment
98% Positive positives Association
80% Positive Psoria only